

Hazard Analysis Worksheet

STEP #10: *Understand the potential hazard.*

Certain food and color additives can cause an allergic-type reaction in consumers. Examples of such food and color additives that are used on fish and fishery products include: sulfiting agents and FD&C Yellow #5. Sulfiting agents are mostly used during on-board handling of shrimp and lobster to prevent the formation of “black spot.” FD&C Yellow #5 is used during in-plant processing. These food and color additives are permitted for use in foods, with certain restrictions, but their presence must be declared on the label. This label declaration is particularly important to sensitive individuals.

Other food and color additives are prohibited from use in food because of a determination by FDA that they present a potential risk to the public health. Examples of such food additives include: cyclamate and its derivatives, safrole, and FD&C Red #4.

STEP #11: *Determine if this potential hazard is significant*

At each processing step, determine whether “food and color additives” is a significant hazard. The criteria are:

1. Is it reasonably likely that a food or color additive that can cause an allergic-type reaction (e.g. sulfiting agents or FD&C yellow #5) or a prohibited substance (e.g. cyclamate and its derivatives, safrole, and FD&C Red #4) will be introduced at this processing step (e.g. does it come in with the raw material or will the process introduce it)?

For example, under ordinary circumstances, it would be reasonably likely to expect that food or color additives that can cause an allergic-type reaction could enter the process under the following circumstances:

- Sulfiting agents may be used on shrimp and lobster between capture and delivery to the processor. However, in some regions even with these products (e.g. some aquacultured shrimp) this practice may not be reasonably likely. You need only identify this potential hazard as significant at your receiving step if you are the first processor to receive the product from the fisherman or aquacultural producer. If you are receiving the product from another processor you may rely upon controls by the primary processor;
- FD&C Yellow #5 may be used in the processing of formulated fishery products or in the production of smoked fish.

2. Can the hazard be eliminated or reduced to an acceptable level here? (Note: If you are not certain of the answer to this question at this time, you may answer “No.” However, you may need to change this answer when you assign critical control points in Step #12)

“Food and color additives” should be considered a significant hazard at a processing step if a preventive measure is or can be used to prevent or eliminate the hazard or is adequate to reduce the likelihood of occurrence of the hazard to an acceptable level, if it is reasonably likely to occur. Preventive measures for allergic-type reactions that can result from the presence of certain food and color additives (e.g. sulfiting agents and FD&C yellow #5) could include:

- Declaring the presence of food and color additives that can cause an allergic-type reaction on finished product labeling;
- Testing incoming shrimp or lobster for residues of sulfiting agents;
- Receiving a supplier’s certification of the lack of sulfiting agent use on incoming lots of shrimp or lobster (with appropriate verification – see Step #18).

A preventive measure for the presence of prohibited food and color additives could include:

- Testing incoming lots of fish for the presence of prohibited food and color additives which there is reason to believe may be present.
- Receiving a supplier’s certification that prohibited food and color additives were not used on the incoming lot of fish (with appropriate verification – see Step #18).

List such preventive measures in Column 5 of the Hazard Analysis Worksheet at the appropriate processing step(s).

If the answer to either question 1 or 2 is “Yes” the potential hazard is significant at that step in the process and you should answer “Yes” in Column 3 of the Hazard Analysis Worksheet. If neither criterion is met you should answer “No.” You should record the reason for your “Yes” or “No” answer in Column 4. You need not complete Steps #12 through 18 for this hazard for those processing steps where you have recorded a “No.”

It is important to note that identifying this hazard as significant at a processing step does not mean that it must be controlled at that processing step. The next step will help you determine where in the process the critical control point is located.

• **Intended use**

In determining whether a hazard is significant you should also consider the intended use of the product, which you developed in Step #4. However, in the case of food additives, it is not likely that the significance of the hazard will be affected by the intended use of the product.

STEP #12: Identify the critical control points (CCP).

For each processing step where “food and color additives” is identified in Column 3 of the Hazard Analysis Worksheet as a significant hazard, determine whether it is necessary to exercise control at that step in order to control the hazard. Figure #2 (Appendix 3) is a CCP decision tree that can be used to aid you in your determination.

The following guidance will also assist you in determining whether a processing step is a CCP for “food and color additives”:

1. In the case of shrimp or lobster for which you have identified sulfiting agents as a significant hazard, will the finished product label declare the presence of sulfiting agents?

- a. If it will, you may identify the finished product labeling step as the CCP. Alternately, you may identify the receipt of product labels as the CCP (where you can check labels for the presence of a sulfiting agent declaration). The raw material receiving step would then not require control and would not need to be identified as a CCP for the hazard of improper use of food and color additives.

In this case enter “Yes” in Column 6 of the Hazard Analysis Worksheet for the finished product labeling step or receipt of product labels step, and enter “No” for the raw material receiving step. In addition, for the raw material receiving step enter in Column 5 that the hazard is controlled by the finished product labeling step or the receipt of product labels step. (Note: if you have not previously identified “food and color additives” as a significant hazard at the finished product labeling step or receipt of product labels step in Column 3 of the Hazard Analysis Worksheet, you should change the entry in Column 3 to “Yes”.) This control approach will be referred to as “Control Strategy Example 1” in Steps #14 through 18.

Example:

A frozen shrimp processor that receives shrimp directly from the harvest vessel and labels all finished product with a sulfiting agent declaration could set the critical control point for sulfiting agents (food and color additives) at the finished product labeling step. The processor would not need to have a critical control point for this hazard at the shrimp receiving step.

- b. If the finished product labeling will not declare the presence of sulfiting agents, you may identify the raw material receiving step as the CCP.

In this case enter “Yes” in Column 6 of the Hazard Analysis Worksheet for the raw material receiving step. This control approach will be referred to as “Control Strategy Example 2” in Steps #14 through 18.

Example:

A frozen shrimp processor that receives shrimp directly from the harvest vessel and does not label finished product with a sulfiting agent declaration could set the critical control point for sulfiting agents (food and color additives) at the raw material receiving step and test incoming lots of shrimp for the presence of sulfiting agents. The processor would not need to have a critical control point for this hazard at finished product labeling.

- c. If the finished product labeling will only declare the presence of sulfiting agents when it is present in the raw material, you may identify the finished product labeling step or the receipt of product labels step (where you can check labels for the presence of a sulfiting agent declaration) as the CCP. Testing at the raw material receiving step will be necessary to ensure control at the CCP. However, the raw material receiving step would not need to be identified as a CCP for the hazard of “food and color additives.”

In this case enter “Yes” in Column 6 of the Hazard Analysis Worksheet for the finished product labeling step or the receipt of product labels step, and enter “No” for the raw material receiving step. In addition, for the raw material receiving step enter in Column 5 that the hazard is controlled by the finished product labeling step or the receipt of product labels step. (Note: if you have not previously identified “food and color additives” as a significant hazard at the finished product labeling step or receipt of product labels step in Column 3 of the Hazard Analysis Worksheet, you should change the entry in Column 3 to “Yes”.) This control approach will be referred to as “Control Strategy Example 3” in Steps #14 through 18.

Example:

A frozen shrimp processor that receives shrimp directly from the harvest vessel and labels finished product with a sulfiting agent declaration only if testing at receipt identifies a residue of a sulfiting agent could set the critical control point for sulfiting agents (food and color additives) at the finished product labeling step or the receipt of product labels step. The processor would not need to have a critical control point for this hazard at the raw material receiving step.

- 2. In the case of products for which you have identified FD&C Yellow #5 as a significant hazard, you should identify the finished product labeling step or receipt of product labels step (where you can check labels for the presence of a FD&C Yellow #5 declaration) as the CCP. The processing step at which you add FD&C Yellow #5 would then not require control and would not need to be identified as a CCP for the hazard of “food and color additives.”

In this case enter “Yes” in Column 6 of the Hazard Analysis Worksheet for the finished product labeling step or receipt of product labels step, and enter “No” for the treatment step. In addition, for the treatment step enter in Column 5 that the hazard is controlled by the finished product labeling step or receipt of product labels step. (Note: if you have not previously identified “food and color additives” as a significant hazard at the finished product labeling step or receipt of product labels step in Column 3 of the Hazard Analysis Worksheet, you should change the entry in Column 3 to “Yes”.) This control approach will also be referred to as “Control Strategy Example 1” in Steps #14 through 18.

Example:

A smoked sablefish processor that treats the fish with FD&C Yellow #5 before smoking could set the critical control point for FD&C Yellow #5 (food and color additives) at the finished product labeling step or receipt of product labels step. The processor would not need to have a critical control point for this hazard at the treatment step.

3. In the case of products for which you have identified prohibited food and color additives (e.g. cyclamate and its derivatives, safrole, and FD&C Red #4) as a significant hazard in incoming raw materials you should identify the raw material receiving step as the CCP.

In this case enter “Yes” in Column 6 of the Hazard Analysis Worksheet for the raw material receiving step. This control approach will be referred to as “Control Strategy Example 2” in Steps #14 through 18.

It is important to note that you may select a control strategy that is different from those which are suggested above, provided that it assures an equivalent degree of safety of the product.

Proceed to Step #13 (Chapter 2) or to Step #10 of the next potential hazard.

HACCP Plan Form

STEP #14: *Set the critical limits (CL).*

For each processing step where “food and color additives” is identified as a significant hazard on the HACCP Plan Form identify the maximum or minimum value to which a feature of the process must be controlled in order to control the hazard.

You should set the CL at the point that if not met the safety of the product may be questionable. If you set a more restrictive CL you could, as a result, be required to take corrective action when no safety concern actually exists. On the other hand, if you set a CL that is too loose you could, as a result, allow unsafe product to reach the consumer.

As a practical matter it may be advisable to set an operating limit that is more restrictive than the CL. In this way you can adjust the process when the operating limit is triggered, but before a triggering of the CL would require you to take corrective action. You should set operating limits based on your experience with the variability of your operation and with the closeness of typical operating values to the CL.

Following is guidance on setting critical limits for the control strategy examples discussed in Step #12.

• Control Strategy Example 1 - Labeling controls

CRITICAL LIMIT: All finished product labels must contain a sulfiting agent or FD&C Yellow #5 declaration, as appropriate.

• Control Strategy Example 2 - Raw material screening

CRITICAL LIMIT: Incoming lots of shrimp or lobster must not contain a detectable level of sulfite, or prohibited food and color additives;

OR

Incoming lots of shrimp or lobster must be accompanied by a supplier’s lot-by-lot certificate that sulfiting agents, or prohibited food and color additives, as appropriate, were not used.

• Control Strategy Example 3 - Labeling controls with raw material screening

CRITICAL LIMIT: Finished product labels for product processed from sulfite-containing raw materials must contain a sulfiting agent declaration.

Enter the critical limit(s) in Column 3 of the HACCP Plan Form.

STEP #15: *Establish monitoring procedures.*

For each processing step where “food and color additives” is identified as a significant hazard on the HACCP Plan Form, describe monitoring procedures that will ensure that the critical limits are consistently met.

To fully describe your monitoring program you should answer four questions: 1) What will be monitored? 2) How will it be monitored? 3) How often will it be monitored (frequency)? 4) Who will perform the monitoring?

It is important for you to keep in mind that the feature of the process that you monitor and the method of monitoring should enable you to determine whether the CL is being met. That is, the monitoring process should directly measure the feature for which you have established a CL.

You should monitor often enough so that the normal variability in the values of the feature you are measuring will be detected. This is especially true if these values are typically close to the CL. Additionally, the greater the time span between measurements the more product you are putting at risk should a measurement show that a CL has been violated.

Following is guidance on establishing monitoring procedures for the control strategy examples discussed in Step #12. Note that the monitoring frequencies that are provided are intended to be considered as minimum recommendations, and may not be adequate in all cases.

What Will Be Monitored?

- Control Strategy Example 1 - Labeling controls

WHAT: Finished product labels for presence of sulfiting agent or FD&C Yellow #5 declaration, as appropriate.

- Control Strategy Example 2 - Raw material screening

WHAT: Representative sample of each lot at receipt for sulfiting agent residual analysis, or prohibited food and color additive residual analysis, as appropriate;

OR

Supplier's lot-by-lot certificate that no sulfiting agent, or prohibited food and color additive, as appropriate, was used on the lot (with appropriate verification – see Step #18).

- Control Strategy Example 3 - Labeling controls with raw material screening

WHAT: Finished product labels for presence of sulfiting agent declaration;

AND

One of the following:

- Representative sample of each lot for sulfiting agent residual analysis;

OR

- Supplier's lot-by-lot certificate that no sulfiting agent was used on the lot (with appropriate verification – see Step #18).

How Will Monitoring Be Done?

- Control Strategy Example 1 - Labeling controls

HOW: Visual examination.

- Control Strategy Example 2 - Raw material screening

HOW: Screening test for sulfiting agents or prohibited food and color additives, as appropriate;

OR

Visual examination of certificates.

- Control Strategy Example 3 - Labeling controls with raw material screening

HOW: Visual examination of labels;

AND

One of the following:

- Screening test for sulfiting agents;

OR

- Visual examination of certificates.

How Often Will Monitoring Be Done (Frequency)?

- Control Strategy Example 1 - Labeling controls

FREQUENCY: At least one label from every case of labels or one label from each pallet of pre-labeled packaging material delivered to the packaging area;

OR

At least one label from every case of labels or pre-labeled packaging material received at the firm.

OR

Once per day for on-site computer generated labels.

- **Control Strategy Example 2 - Raw material screening**

FREQUENCY: Each incoming lot.

- **Control Strategy Example 3 - Labeling controls with raw material screening**

FREQUENCY: At least one label from every case of labels or one label from each pallet of pre-labeled packaging material delivered to the packaging area;

OR

At least one label from every case of labels or pre-labeled packaging material received at the firm.

OR

Once per day for on-site computer generated labels.

AND

Each lot of incoming shrimp or lobster.

Who Will Perform the Monitoring?

- **Control Strategy Example 1 - Labeling controls**

WHO: Monitoring may be performed by the labeling equipment operator, the receiving employee, a production supervisor, a member of the quality control staff, or any other person who has an understanding of the proper content of the label.

- **Control Strategy Example 2 - Raw material screening**

WHO: Monitoring may be performed by the receiving employee, a production supervisor, a member of the quality control staff, or any other person who that has an understanding of the proper screening procedure. Assignment of responsibility for testing procedures should be based, in part, on the degree of difficulty of the analysis.

- **Control Strategy Example 3 - Labeling controls with raw material screening**

WHO: Monitoring may be performed by the labeling equipment operator, the receiving employee, a production supervisor, a member of the quality control staff, or any other person who that has an

understanding of proper content of the label or the screening procedure, as appropriate. Assignment of responsibility for testing procedures should be based, in part, on the degree of difficulty of the analysis.

Enter the “What,” “How,” “Frequency,” and “Who” monitoring information in Columns 4, 5, 6, and 7, respectively, of the HACCP Plan Form.

STEP #16: *Establish corrective action procedures.*

For each processing step where “food and color additives” is identified as a significant hazard on the HACCP Plan Form, describe the procedures that you will use when your monitoring indicates that the CL has not been met.

These procedures should: 1) ensure that unsafe product does not reach the consumer; and, 2) correct the problem that caused the CL deviation. Remember that deviations from operating limits do not need to result in formal corrective actions.

Following is guidance on establishing corrective action procedures for the control strategy examples discussed in Step #12.

- **Control Strategy Example 1 - Labeling controls**

CORRECTIVE ACTION: Segregate and relabel any improperly labeled product;

AND

Segregate and return or destroy any label stock or pre-labeled packaging stock that does not contain the proper declaration.

- **Control Strategy Example 2 - Raw material screening**

CORRECTIVE ACTION: Reject any incoming lot in which sulfiting agent or prohibited food and color additive, as appropriate, is detected or which is not accompanied by a supplier’s certificate.

- **Control Strategy Example 3 - Labeling controls with raw material screening**

CORRECTIVE ACTION: Segregate and relabel any improperly labeled product;

AND

Segregate and return or destroy any label stock or pre-labeled packaging stock that does not contain the proper declaration.

Enter the corrective action procedures in Column 8 of the HACCP Plan Form.

STEP #17: Establish a recordkeeping system.

For each processing step where “food and color additives” is identified as a significant hazard on the HACCP Plan Form, list the records that will be used to document the accomplishment of the monitoring procedures discussed in Step #15. The records should clearly demonstrate that the monitoring procedures have been followed, and should contain the actual values and observations obtained during monitoring.

Following is guidance on establishing a record-keeping system for the control strategy examples discussed in Step #12.

- **Control Strategy Example 1 - Labeling controls**

RECORDS: Record of labeling checks.

- **Control Strategy Example 2 - Raw material screening**

RECORDS: Test results for sulfiting agent or prohibited food and color additives, as appropriate;
OR
Supplier’s lot-by-lot certificates.

- **Control Strategy Example 3 - Labeling controls with raw material screening**

RECORDS: Record of labeling checks;
AND

One of the following:

- Sulfiting agent test results;

OR

- Supplier’s lot-by-lot certificates.

Enter the names of the HACCP records in Column 9 of the HACCP Plan Form.

STEP #18: Establish verification procedures.

For each processing step where “food and color additives” is identified as a significant hazard on the HACCP Plan Form, establish verification procedures that will ensure that the HACCP plan is: 1) adequate to address the hazard of improper use of food and color additives; and, 2) consistently being followed.

Following is guidance on establishing verification procedures for the control strategy examples discussed in Step #12.

- **Control Strategy Example 1 - Labeling controls**

VERIFICATION: Review monitoring and corrective action records within one week of preparation.

- **Control Strategy Example 2 - Raw material screening**

VERIFICATION: Review monitoring, corrective action, and, where applicable, verification records within one week of preparation;

AND

When supplier’s guarantees are used for monitoring, collect at least one representative sample per quarter, randomly selected from among your suppliers, and analyze for sulfiting agents or prohibited food and color additives, as appropriate. Additionally, collect at least one representative sample for each new supplier, and analyze for sulfiting agents or prohibited food and color additives, as appropriate.

- **Control Strategy Example 3 - Labeling controls with raw material screening**

VERIFICATION: Review monitoring, corrective action, and, where applicable, verification records within one week of preparation;

AND

When supplier’s guarantees are used for monitoring, collect at least one representative sample per quarter, randomly selected from among your suppliers, and analyze for sulfiting agents. Additionally, collect at least one representative sample for each new supplier, and analyze for sulfiting agents.

Enter the verification procedures in Column 10 of the HACCP Plan Form.

TABLE #19-1

Control Strategy Example 1 - Labeling controls

This table is an example of a portion of a HACCP plan relating to the control of sulfiting agents for a processor of wild-caught shrimp, using Control Strategy Example 1 – Labeling controls. It is provided for illustrative purposes only. Food and color additives may be only one of several significant hazards for this product. Refer to Tables 3-1, 3-2, and 3-3 (Chapter 3) for other potential hazards (e.g. chemical contaminants, food and color additives, and metal fragments).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4)			(5) Monitoring		(6)		(7)	(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who	Frequency	Who					
Labeling receipt	Sulfiting agents	All finished product labels must contain sulfiting agent declaration	Finished product labels for presence of sulfiting agent declaration	Visual	One label from each case of labels at receipt	Receiving employee	Receiving employee	One label from each case of labels at receipt	Receiving employee	Segregate and return any labels that do not contain the sulfiting agent declaration	Label receiving record	Review monitoring and correction action records within one week of preparation	

TABLE #19-2

Control Strategy Example 2 - Raw material screening

This table is an example of a portion of a HACCP plan relating to the control of sulfiting agents for a processor of wild-caught frozen shrimp, using Control Strategy Example 2 – Raw material screening. It is provided for illustrative purposes only. Food and color additives may be only one of several significant hazards for this product. Refer to Tables 3-1, 3-2, and 3-3 (Chapter 3) for other potential hazards (e.g. chemical contaminants, food and color additives, and metal fragments).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4)			(5) Monitoring		(6)		(7)	(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who	Frequency	Who					
Shrimp receiving	Sulfiting agents	Incoming lots of shrimp must be accompanied by a supplier's guarantee that sulfiting agents were not used on the lot	Supplier's lot-by-lot guarantee that no sulfiting agents were used on the lot	Visual	Every lot of incoming shrimp	Receiving employee	Reject any incoming lot of shrimp that is not accompanied by a supplier's guarantee	Copies of supplier's guarantees	<ul style="list-style-type: none"> Test one lot per quarter for sulfiting agent residue, and test one lot from each new supplier of shrimp for sulfiting agent residue Review monitoring, correction action and verification records within one week of preparation 				

TABLE #19-3

Control Strategy Example 3 - Labeling controls with raw material screening

This table is an example of a portion of a HACCP plan relating to the control of sulfiting agents for a processor of wild-caught frozen shrimp, using Control Strategy Example 3 – Labeling controls with raw material screening. It is provided for illustrative purposes only. Food and color additives may be only one of several significant hazards for this product. Refer to Tables 3-1, 3-2, and 3-3 (Chapter 3) for other potential hazards (e.g. chemical contaminants, food and color additives, and metal fragments).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4)			(5) Monitoring		(6)		(7)		(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who	Who	Who						
Finished product labeling	Sulfiting agents	Finished product labels for product processed from sulfite-containing raw material shrimp must contain a sulfiting agent declaration	<ul style="list-style-type: none"> Finished product labels for presence of sulfiting agent declaration Three shrimp collected randomly from each lot of raw material shrimp for sulfiting agent residual analysis 	<ul style="list-style-type: none"> Visual malachite green test 	<ul style="list-style-type: none"> One label from each case of labels delivered to packaging Three shrimp from each lot of raw material shrimp 	<ul style="list-style-type: none"> Packaging machine operator Quality control employee 	<ul style="list-style-type: none"> Segregate and relabel any improperly labeled product Segregate and return any label stock that does not contain the proper declaration 	Label check record	<ul style="list-style-type: none"> Review monitoring and corrective action records within one week of preparation 					